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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,533

Applicant(s)

COUTTS ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12/3/04.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 106-128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims:

Claims pending in the application are 22,23,26,32,35,36,38,43,45,46,51-54,64-77,79-82,84,86,89 and 99-133.

Continuation of Disposition of Claims:

Claims withdrawn from consideration are 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-105, 129-133

Pursuant to the amendment filed 12/3/04, claims 22, 45, 64, 67, 68, 75, 77, 80, 84, 89 have been amended, claims 99-133 added, and the following claims cancelled: 24, 25, 27-31, 33, 34, 37, 39-42, 44, 47-50, 55-63, 78, 83, 85, 87, 88, 90-98. Claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89 and 99-133 are now pending.

Applicants' arguments filed 12/3/04 have been considered and found persuasive in part. the previously imposed §103 rejections are withdrawn. In addition, the "ODP" rejections over the following documents are withdrawn: USP 6060056, USSN 09/753350, and USSN 09/590,592.

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The following abbreviations are used hereinbelow:

"VPM" denotes a "valency platform molecule".

"BAM" denotes a "biologically active molecule".

"PEG" denotes polyethylene glycol.

"TEG" denotes triethylene glycol.



Newly submitted claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-105, 129-133 are directed to an invention that is independent or distinct from the invention originally claimed.

Previously, the claimed invention was a conjugate comprising a VPM and several

BAM's, wherein there were no structural limitations on the VPM. Now, the VPM must contain ethylene glycol, and have a specific molecular weight.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-105, 129-133 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 106-128 are examined in this Office action.



Claim 106 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. USP 5,276,013.

This ground of rejection was imposed in the previous Office action. In response, applicants have argued the following:

“This rejection therefore appears to be based in a second premise, that a species (1) which is disclosed in a patent specification, (2) which is within the scope of a generic claim, and (3) which is not otherwise suggested by that generic claim, may be used to reject a later-filed patent claim that also claims that species under the doctrine of obviousness-type double patenting. Both premises are incorrect.”

Applicants have argued essentially that claims must be read in a vacuum. This is because, according to applicants, the description of the invention within a given patent somehow qualifies as “prior art”, and applicants are barred from using the disclosure of a patent as

prior art. However, the examiner is not using the disclosure of the patent as “prior art”. Rather, the examiner is referring to the disclosure of the patent as evidence of what is encompassed by the claims at issue.

Additionally, applicants have pointed to *In re Kaplan* (229 USPQ 678, 1986), which pertains to what is now US Patent 4,626,551. During prosecution of the ‘551 application (Serial number 06/364221), the BPAI imposed an ODP rejection over USP 3,944,588, which the CAFC subsequently reversed. Let “G1” represent the claimed genus of a first patent, and “G2” represent the claimed genus of a second patent, wherein G1 is substantially broader than G2 and wherein the application of first patent is filed before the application of the second patent. To paraphrase applicants’ argument, applicants have argued that the Kaplan decision supports the proposition that examiners are barred from using claims drawn to G1 as a basis for an ODP rejection against claims drawn to G2. The examiner would disagree, however. The first point with regard to Kaplan is whether the Court was aware that the tetraglyme/sulfolane solvent mixture was disclosed in the earlier patent (USP ‘588). As it happens, this mixture was disclosed in table VI, example 45. There is nothing in the Court opinion to indicate a recognition of the disclosure of this mixture. Indeed the language of the opinion suggests that the recitation of this mixture was not recognized. Consider the following passage from the opinion:

“Is this an extension of a patent on Kaplan's invention -- Kaplan who never conceived of using that mixture? When Kaplan's (sole) patent expires, and

assuming appellants get their joint patent, the world will still be free to use (so far as these two patents go) the Kaplan process so long as appellants' solvent mixture is not used in it. Of course, it may be that everyone will want to use the improvement, but that is commonly the case when dominating patents expire with improvement patents still outstanding”

Thus, the Court specifically implies that Kaplan ‘588 does not disclose the tetraglyme/sulfolane solvent mixture (which is contrary to what the patent discloses). But even if one assumes that the Court recognized the disclosure of the tetraglyme/sulfolane solvent mixture, and chose not to make reference to it, there is another matter, which pertains to the following phrase in claim 1 of USP ‘551:

“...the improvement which comprises effecting said reaction in a solvent mixture of tetraglyme and sulfolane under conditions whereby such solvent mixture is essentially inert and the rate of formation of such alkane polyol is greater than would be obtained by effecting said reaction under equal conditions using tetraglyme or sulfolane as the solvent.”

Thus, the ‘588 patent makes only a passing mention of the tetraglyme/sulfolane solvent mixture, and does not suggest that the rate of formation of the alkane polyol would be any greater when the solvent mixture is used than would be the case if either solvent (tetraglyme or sulfolane) were used alone. The ‘551 patent requires that there be specific advantages realized by the use of the binary mixture (tetraglyme/sulfolane), and the implication is that if these advantages are not realized by a given set of reaction conditions, the patent does not cover it.

One may contrast the foregoing case with the instant case, where there is no structural difference, i.e., there is at least one compound encompassed by the patented claim (and explicitly disclosed in the issued patent) which is also encompassed by the instant claim. Nor is there any difference with regard to how to use the compounds, since the claims at issue are drawn to compounds *per se*, and not methods of use. Accordingly, *In re Kaplan* does not confer “immunity” from ODP rejections in cases where “G1” is used as the basis for rejection of “G2” (as these genera are explained above).

The rejection is maintained.



Claim 106 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. USP 5,552,391. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In response to this rejection, applicants have not traversed the rejection, stating only that the issue will be addressed at a later time. Accordingly, the rejection is maintained without further comment.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 106-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 106 recites the following: “an ethyleneoxide containing ...VPM”.

First, there is no descriptive support for any and all VPM's containing ethylene oxide, but even if such support existed, there is not support for such an ethyleneoxide containing VPM in combination with the other structural features (i.e., diamino acid or triamine or amino diacid and four attachment sites and a multiplicity of polynucleotides).

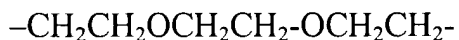
Applicants have argued that descriptive support can be found at the following locations:

- a) p. 4, line 30-34
- b) page 19, line 14 – page 20, line 9
- c) reaction schemes on pages 32-34 and 37

However, the text and figures at these locations do not provide adequate descriptive support for the claimed invention. Consider first page 4, lines 30+. It is true that $G^{[2]}$ can be $-CH_2(CH_2OCH_2)_rCH_2-$, wherein “r” is in the range of zero to 300. If “r” is zero, the result is not ethylene oxide, or anything that contains ethylene oxide.

And if “r” is one, the result is again a substituent that does not contain ethylene oxide.

For the case of “r” being 2, the result is the following:

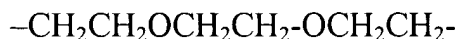


As it happens, the term “ethylene oxide” does not appear anywhere in the specification.

The term at issue actually refers to the epoxidation product of ethylene, i.e., $\text{C}_2\text{H}_4\text{O}$.

In a very simplistic sense, one could argue that, since the term “ethylene oxide” does not appear anywhere in the specification, descriptive support is lacking for the claimed invention for that reason alone. However, it is well known to the polymer chemist of ordinary skill that ethylene oxide will readily undergo polymerization reactions.

Perhaps one could thus argue that applicants intended for the claim to recite *ethylene glycol-containing*, rather than “ethylene oxide-containing”. Turning back to page 4, lines 30+ (specification), when “r” is 2, the result is the following:



It is true that this is an “ethylene glycol-containing” group, but it is not ethylene glycol *per se*, nor is it polyethylene glycol *per se*. In fact, regardless of what “r” may be, the result is not ethylene glycol or polyethylene glycol (and is certainly not ethylene oxide).

At best, what the cited passage on page 4 conveys is that for values of “r” above 1, the result is either ethylene glycol bearing an ethylene group at each terminal position, or an oligomer of ethylene glycol, again bearing an ethylene group at each terminal position.

But in any case, the cited passage does not provide support for any ethylene glycol-containing VPM (or any ethylene oxide- containing VPM).

Consider next page 19, line 14+. The only relevant passage is present on page 20, lines 7-9, which mentions TEG and PEG's. However, the TEG and PEG's must be confined to a molecular weight of 200-8000 g/mol, a limitation which is not mentioned in the claims. In addition, the passage in question makes no reference to the other structural features of the claims (i.e., diamino acid or triamine or amino diacid and four attachment sites and a multiplicity of polynucleotides). Consider next the reaction schemes on pages 32-34 and 37. It is true that examples of compounds containing 1-3 ethylene glycol units are disclosed. However, neither a single specie, nor a handful of species, defines a genus.

- In *In re Smith* 173 USPQ 679, 1972 pertained to an emulsion coating composition in which a pigment is coated with an organic compound. The court found that a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads. In the instant case the "genus" could be viewed as original claim 1, and the subgenus current claim 20. In the instant case, claim 20 has been fashioned on the basis of the original genus, together with six (or perhaps seven) species. As with the Smith case, these six peptide species do not amount to a description of the claimed genus.
- *Tronzo v. Biomet* (47 USPQ2d at 1829 1998) pertained to what is now USP 4,743,262, in which the claims are drawn to an acetabular cup prothesis. The issue concerned written description of a priority document, which is closely allied with the issue of new matter. The court found that claims to a generic cup shape were not entitled to filing date of parent application which disclosed only a conical cup. Thus, one could conclude that an extrapolation from a specie to a genus would constitute new matter.

- The claims in *In re Sus* (134 USPQ 301 1962) were drawn to light-sensitive aryl azides. The issue was whether the structural formula recited in the claims (especially the term "substituted aryl") was adequately supported by a general description of the claimed invention, together with the disclosure of several species. The court found that the claimed genus was not adequately described by disclosure of several species, even when taken together with a general description of the claimed invention. Such is the case here.

An attempt has been made in the instant case to create a genus which shares a few of the features of several species. Such an extrapolation constitutes new matter. See also *In re Curtis* (69 USPQ2d 1274, CA FC 2004).

Thus, what applicants have done is to first point to the genera on page 4 of the specification. However, these genera are so broad as to encompass almost any molecule that one can imagine. As such, these genera do not describe the claimed genus. Next, applicants have pointed to species, some of which do fall within the scope of the claimed invention. However, neither the species taken alone, or in combination with the genera on page 4 provide adequate descriptive support for the claimed genus.

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Claims 108, 112, ~~138~~ are rejected under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the phrase “at least about”, thus rendering the claims indefinite as to the lower limit of the range.

Claim 112 recites “suitable for reducing antibody levels”. What is the context? For example, can the conjugate be used to reduce antibody levels in a test tube, or in a plant, or in an insect?

Claim 126 is dependent on a non-elected claim.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Reference 12 (DD 287950) was stricken from the IDS because a translation has not been provided.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1400